

ISO 13485 Mapping : Process and Product

Verification and Validation

ระบุประเภทเครื่องมือแพทย์

ISO 13485

ระบุกิจกรรมที่เกี่ยวข้องกับเครื่องมือแพทย์

OR

Medical Device

Parts of Medical Device /
Component Parts /
Services for Medical
devices
Calibration / Distribution

ISO14971
Risk Management

Customer
Requirements

IVD

ISO14971
Risk Management

Design

Non Active

ISO14971
Risk Management

Design

Active MD

ISO14971
Risk Management

Design

GHTF Process Validation
ISO 13612
ISO13532 Self test
ISO11135 , ISO 11137
Sterilization (If any)
ISO11607 Packaging
Clinical Trial /Review
etc

Regulation / Pre & Post Market

GHTF Process Validation
ISO11135 , ISO 11137
ISO10993
ISO11607 Packaging / Sealing
validation
ISO11737-1, ISO 11737-2
ASTM1980 Shelf life test
Clinical Trial /Review
Etc.

Regulation / Pre & Post Market

- IEC 60601-1 Safety
- IEC 60601-2 EMC
- IEC 60601-4 Use
- IEC 62304 Software
- IEC 62366
- Clinical Trial /Review
- Etc.

Regulation / Pre & Post Market



www.qtimeconsult.com

